HIMA
HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

August 13, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 99N-1220; Draft Civil Money Penalty Reduction Policy for Small Entities; Comments of Health Industry Manufacturers Association

Dear Sir or Madam:

The Health Industry Manufacturers Association (HIMA) hereby submits its written comments on the Food and Drug Administration's (FDA) Draft Civil Money Penalty Reduction Policy for Small Entities ("Draft Policy"), which was published in the Federal Register. See 64 Fed. Reg. 26984-86 (May 18, 1999).

HIMA is the largest medical technology association in the world for manufacturers of medical devices, diagnostics and health information systems. HIMA has 304 member firms, representing the interests of more than 800 individual divisions and subsidiaries located throughout the world. Annually, HIMA members provide nearly 90 percent of the $62 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $147 billion purchased abroad.

Of HIMA's more than 304 members, 228 qualify as "small entities" under the Small Business Regulatory Enforcement Fairness Act (SBREFA). These small entities, like HIMA's larger members, are regulated by the FDA under the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

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HIMA and its "small entity" members wish to support the agency in its efforts to adopt a formal written policy on civil money penalty (CMP) reductions and waivers for small entities, and appreciates the Agency complying with its Good Guidance Practices Procedures. Establishment of such a policy became a requirement for all Federal agencies that regulate the activities of small entities with the enactment of Section 223 of SBREFA, P. L. No. 104-121, § 251-253, 110 Stat. 862 (1996). The Draft Policy also complies with the Presidential Memorandum of April 21, 1995, which also directed agencies to modify civil penalties for small businesses. The Draft Policy contains provisions that are derived both from Section 223 of SBREFA and the Presidential Memorandum.

HIMA's comments on the Draft Policy essentially request FDA to clarify and augment various sections. HIMA's detailed comments are provided below.

1. The Draft Policy Should Make Clear That FFDCA § 303(f) Is The Starting Point For Small Device Entity Civil Penalty Analysis

Section 303(f) of the FFDCA, codified as 21 U.S.C. § 333(f), and enacted as part of the Safe Medical Devices Act of 1990 (SMDA), P. L. No. 101-629, 104 Stat. 4511 (1990), provides for the issuance of civil money penalties for device violations. Concerning the factors to be used in setting the amount of a civil penalty, Section 303(f)(3)(B) of the FFDCA, 21 U.S.C. § 333(f)(3)(B), reads as follows:

> In determining the amount of a civil penalty [for a device violation of the FFDCA], the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations, and with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

Once a civil penalty has been set, the statute gives the FDA broad power to depart from the stated amount for a medical device violation. The statute says the FDA "may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed [for a device violation]." 21 U.S.C. § 333(f)(3)(C).

Section 303(f) (and any guidance document addressing it) must be the starting point for all small device entity civil penalty analysis, and the Draft Policy must build upon Section 303(f). The Draft Policy must be revised to make this point explicit and clear. Such clarification will avoid any confusion that the Draft Policy is a substitute for analysis under Section 303(f)(3)(B) or that the Draft Policy sets up a new parallel scheme for determining the amount of a civil money penalty

initially.

If such confusion took root, the civil penalty criteria for small entities outlined in the Draft Policy would offer less protection for small device entities than the statutory scheme under Section 303(f) of the FFDCA. By way of illustration, HIMA below discusses two key examples of how the Draft Policy would conflict with Section 303(f) if it were mistakenly applied as a substitute for the statute.

a. Draft Policy on Prior Violation History As Compared To Section 303(f) of FFDCA

When the FDA determines the amount of a civil penalty for a device violation, it must consider whether the violator has "any history of prior . . . violations" pursuant to Section 303(f)(B)(3). There is no command in the statute that, if a firm has had a prior violation recently, this will be an absolute bar to adjusting the civil penalty for a current violation. Rather, this statute gives the agency full latitude to give appropriate weight to a history of prior violations on a case-by-case basis. This applies whether the violator is a small entity or a large business. HIMA supports this flexible statutory approach.

The Draft Policy, on the other hand, sharply limits the FDA's discretion for penalty reduction or waiver when considering a prior violation history. Section A.1. of the Draft Policy states that penalty reduction or waiver will never be available for any small entity if the small entity "was subject to an enforcement action (e.g. seizure, injunction or prosecution) by FDA within the last 5 years, and is still under the same management." 64 Fed. Reg. at 26985. Thus, the Draft Policy provision imposes a definite ban on penalty reduction or waiver under these circumstances. If viewed as a substitute for analysis under Section 303(f), this Draft Policy ban would be in direct conflict with the agency's flexible authority under Section 303(f)(3)(B). In short, the statute permits the FDA to set a lesser civil penalty in an appropriate case, even when the small entity's prior enforcement action occurred less than five years earlier. The Draft Policy should only then be applied to determine whether an even lesser penalty is or is not appropriate.

b. Draft Policy on Small Entity's Ability to Pay As Compared To Section 303(f) of FFDCA

Section 303(f) makes it mandatory for the FDA to take into account the violator's "ability to pay" as well as the civil penalty's effect on the device manufacturer's "ability to continue to do business." 21 U.S.C. § 333(f)(3)(B). By comparison, the "ability to pay" clause in the Draft Policy, Part C, would give small entities in the medical device field less potential for relief, i.e., reduction or waiver, based on ability to pay. The Draft Policy provision reads as follows:

c. FDA may also consider whether to reduce or waive a CMP against a small entity, including a small entity otherwise excluded from this draft policy under paragraph A above, if the small entity can demonstrate to the FDA's satisfaction that it is financially unable to pay the penalty, immediately or over a reasonable period of time, in whole or in part. (Emphasis added.)

This provision is less generous to small entities than the language in Section 303(f) for two reasons. First, the Draft Policy says FDA "may...consider" a small entity's inability to pay. Under Section 303(f) it is mandatory for the agency to consider a violator's "ability to pay," which guarantees that this factor will be taken into account. Second, under Section 303(f), the FDA is required to consider not only the violator's "ability to pay" but also the penalty's "effect on [the violator's] ability to continue to do business." There is no provision in the Draft Policy that requires or permits FDA to consider whether a small entity will be able to remain in business.

These comparisons illustrate why FDA must clarify that Section 303(f) is to be applied first before any consideration is given to the Draft Policy. In short, FDA should make clear that a civil penalty amount should be fully established pursuant to Section 303(f), and then, and only then, should the Draft Policy be applied to determine if a further reduction or waiver is appropriate for a small device entity.

2. Other Comments On The Draft Policy Text

a. HIMA has numerous questions concerning the terms used in the Draft Policy. The terms used in Part A are particularly important, because if any of the four conditions in Part A apply, the FDA would deny a reduction or waiver of penalty on the basis of a firm being a "small entity." In Section A.1. of the Draft Policy, it states that a small entity that has been subject to "an enforcement action (e.g. seizure, injunction or prosecution) within the last 5 years and "is still under the same management" is not eligible to have its CMP reduced or waived. The term "enforcement action" should be clarified and limited to prior seizures, injunctions, and criminal prosecutions upheld through all appeals taken. Otherwise, common enforcement actions, such as a Warning Letter, or judicially-reversed enforcement action, would be enough to qualify as an "enforcement action" that would trigger this provision.

b. The phrase "under the same management" in Section A.1 also needs clarification. If "under the same management" means any or all employees who were in a management role at the time of the earlier enforcement action, then Section A.1 potentially would penalize a small entity that had an enforcement action and did not thereafter dismiss all of its management employees. Alternatively, Section A.1 would penalize a small entity that did not sell

its ownership or control to another party. It potentially would also penalize a new owner who did not dismiss all of the employees who were in management at the time of the earlier enforcement action. Therefore, HIMA believes that Section A.1. should only apply where, since the earlier enforcement action, there has been no change in the firm's management employees responsible for the earlier violation, whether or not the firm's ownership or control has changed.

c. In Section A.2. of the Draft Policy, a determination that any violation by the small entity "involved willful conduct" would cause a small entity to be ineligible for penalty reduction or waiver under the policy. HIMA has two concerns with this provision. First, it is not clear whether this provision applies to prior violations or only to the current violation for which the civil penalty was assessed. HIMA believes the provision should be limited to the latter. Second, HIMA is concerned with how FDA would arrive at a determination that a small entity's violation "involved willful conduct." HIMA proposes that the FDA not apply this factor unless there has first been a judicial ruling that the small entity had engaged in "willful conduct." This change would guard against potential inconsistent application of this provision.

d. In Section A.3. of the Draft Policy, a determination that a small company had not made "a good faith effort to comply with the law" would mean that the company would not be eligible for any penalty reduction or waiver under the Draft Policy. Given the broad nature of what does or does not constitute "good faith," HIMA believes that the agency should establish elements of what qualifies or does not qualify as "a good faith effort to comply with the law."

e. In Section A.4. of the Draft Policy, if the FDA determined that "any of the small entity's violations pose serious health or safety threats," this again would be sufficient to deny any penalty reduction or waiver. HIMA believes that the phrase "pose serious health or safety threats," without further elaboration, is overly broad and allows too much discretion to the agency. HIMA proposes that the FDA revise the Draft Policy to limit application of Section A.4 to situations where the violation directly resulted in a death or "serious injury" (as defined in 21 C.F.R. § 803.3(aa)), at least for small device entities.

f. Following Parts A through D of the Draft Policy, as issued in the Federal Register, there is a section headed "Exclusions from the Draft Penalty Reduction Policy." In this section, the agency mentions an additional factor that could apply when the agency decides whether or not to reduce a civil penalty for a small entity. This factor is presented at 64 Fed. Reg. 26986 as follows:

> If a small entity is eligible for CMP reduction, but has obtained an economic benefit from the violations such that it may have obtained an economic advantage over its

competitors, FDA may seek the full amount of the penalty. (Emphasis added.)

64 Fed. Reg. at 26986.

This language raises the possibility that a small entity could be denied a reduction whenever the FDA determines that there may have been an "economic advantage over its competitors." HIMA believes that the FDA should be required to show that the firm actually gained a certain amount of sales at the expense of its competitors, and that these sales exceeded $250,000 **[or some other amount]** within a one-year period. Alternatively, the FDA could also show that the company saved $250,000 **[or some other amount]** in not taking the required corrective action. Setting a more concrete threshold would prevent the FDA from applying this provision in an arbitrary fashion.

g. The Draft Policy lists three factors, in Part B, that would favor a reduction or waiver in penalty for a small entity. Section B.6. states that in considering whether to reduce or waive a civil penalty, the FDA will consider "[t]he extent to which the small entity cooperated during the investigation." Section B.8. states that the FDA may consider "[w]hether the small entity has engaged in subsequent significant remedial efforts to mitigate the effects of the violations and to prevent future violations." Section B.9. states that another consideration will be "[w]hether the small entity voluntarily reported the violations to FDA promptly after discovering them." Like the other concepts mentioned above, these three concepts deserve further elaboration and establishment of more exacting criteria.

In Chapter 8 of the Federal Sentencing Guidelines, which deals with sentences for organizations, Part C covers the topic of fines on organizations. In this part of the Guidelines, there are provisions that call for lowering fines when organizations maintain an internal program to prevent and detect violations, voluntarily report their violations, or cooperate with the enforcement authorities.

Specifically, § 8C2.5 of the Guidelines, subsection (g), reads as follows:

> (g) Self-Reporting, Cooperation, and Acceptance of Responsibility
>
> If more than one applies, use the greatest:
>
> (1) If the organization (A) prior to an imminent threat of disclosure or government investigation; and (B) within a reasonably prompt time after becoming aware of the offense, reported the offense to appropriate governmental authorities, fully cooperated in the

> investigation, and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct, subtract **5** points; or
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> (2) If the organization fully cooperated in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct, subtract **2** points; or
>
> (3) If the organization clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct, subtract **1** point.

In addition, there is another section of the Federal Sentencing Guidelines that corresponds to the Draft Policy. In § 8C2.5 of the Guidelines, subsection (f), the introductory part of the subsection reads as follows:

> (f) Effective Program to Prevent and Detect Violations of Law
>
> If the offense occurred despite an effective program to prevent and detect violations of law,[1] subtract **3** points.

HIMA believes the same or similar concepts from the Federal Sentencing Guidelines could be adapted for use in the Draft Policy to clarify and augment Sections B.6, B.8 and B.9. FDA should also consider adopting a weighted system for determining small entity penalty reductions and

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[1] The Federal Sentencing Guidelines define "an effective program to prevent and detect violations of law" as having seven elements. Briefly, the organization must have (1) established compliance standards and procedures, (2) assigned specific high level personnel to oversee compliance with these standards, (3) taken due care not to delegate substantial discretionary authority to individuals with a propensity for illegal activities, (4) taken steps to communicate standards and procedures to all employees and other agents, such as through training and publications; (5) taken steps to achieve compliance by, for example, monitoring and auditing systems and ways for employees and other agents to report criminal conduct without fear of retribution, (6) consistently enforced the standards through appropriate discipline both of individuals responsible for offenses and those responsible for failure to detect offenses, and (7) responded appropriately after an offense has been detected. See Federal Sentencing Guidelines, § 8A1.2., Application Note 3(k).

waivers.

3. The Draft Policy Requires Additional Procedures in 21 C.F.R. Part 17

The FDA has promulgated regulations at 21 C.F.R. Part 17 which establish hearing procedures for civil money penalty actions. These regulations provide that, after the agency serves its complaint calling for a civil money penalty, the respondent may request a hearing. If and when the Draft Policy takes effect as a final policy, these hearing procedures should be adapted to insure that relevant firms have the opportunity to present arguments to the Presiding Officer to demonstrate they qualify as a "small entity" and to establish why a "small entity" reduction or waiver is appropriate. HIMA proposes that the agency consider an appropriate revision to the regulations at 21 C.F.R. Part 17 to address this issue.

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HIMA appreciates the opportunity to comment on the Draft Policy.

Respectfully submitted,

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